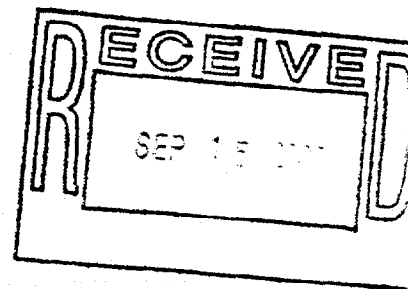


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August 30, 2000



The Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street S.W.  
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Supports a healthy nervous system.
- (2) B-complex vitamins support healthy nerves and brain function. Choline and calcium promote proper nerve impulse transmission between the brain and central nervous system. Glutamic acid is an important amino acid used by the brain as fuel. Inositol has a calming influence on the nerves and assists in forming lecithin. Lecithin makes up a good deal of the protective sheaths that surround the brain.
- (3) Promotes calcium absorption.
- (4) Calcium is needed to keep bones and teeth strong, the heart and vessels healthy, and is required for muscle growth and contraction.
- (5) The amino acid lysine is needed for calcium absorption and is found in both soy and yeast. Vitamin D, found in alfalfa, is needed for calcium utilization. Silicon found in carrot root accelerates calcium absorption.
- (6) Maintains cellular health.
- (7) The vitamins and minerals found in Senaplex™ are natural antioxidants that help protect cells from damage caused by free radicals. Betaine hydrochloride is a compound that performs important metabolic functions at the cellular level.
- (8) With no living, active cells in the nutritional type of yeast, the body can take full advantage of the entire nutritional value of the yeast.

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*Whole Food Supplements*

- (9) *Tillandsia* (Spanish Moss) – found to contain up to twenty-six different compounds in the phytochemical family known as cytoartanes, compounds that can help support joint health.

These statements are made for a dietary supplement containing a proprietary blend of nutritional yeast, choline bitartrate, *Tillandsia usneoides*, bovine liver PMG™ extract, calcium lactate, betaine hydrochloride, defatted wheat (germ), soy (bean), carrot (root), bovine adrenal, bovine brain, inositol, soy bean lecithin, ribonucleic acid, veal bone, bovine kidney, bovine orchic extract, dl-methionine, bovine spleen, ovine spleen, l-lysine mono-hydrochloride, dried alfalfa juice, glutamic acid, rice (bran) extract, and peanut (bran). Other ingredients include gelatin, potassium bicarbonate, water, niacinamide, natural colors, pyridoxal 5-phosphate, ascorbic acid, vitamin A palmitate, riboflavin 5'-phosphate, cholecalciferol, cellulose, and cyanocobalamin. The name of the product is Senaplex™.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden  
Standard Process Inc.

